#### STATE OF MICHIGAN

# DEPARTMENT OF LABOR & ECONOMIC GROWTH

### OFFICE OF FINANCIAL AND INSURANCE REGULATION

Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXX File No. 87962-001

Petitioner

٧

Blue Cross Blue Shield of Michigan Respondent

Issued and entered
This 21<sup>st</sup> day of April 2008
by Ken Ross
Commissioner

#### ORDER

## I PROCEDURAL BACKGROUND

On February 20, 2008, XXXXX, authorized representative of his wife XXXXX (Petitioner), filed a request for external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act (PRIRA), MCL 550.1901 *et seq.* The Commissioner reviewed the material submitted and accepted the request on February 27, 2008.

The Commissioner assigned the case to an independent review organization (IRO) because it involved medical issues. The IRO provided its analysis and recommendations to the Commissioner on March 12, 2007.

## II FACTUAL BACKGROUND

The Petitioner receives health care benefits from Blue Cross Blue Shield of Michigan (BCBSM) under its *Community Blue Group Benefits Certificate* (the certificate).

On March 23, 2007, the Petitioner had laboratory testing for lipoprotein-associated phospholipase A2 (LP-PLA2). The test was requested by her doctor and the charge was \$283.33.

BCBSM denied payment for the Petitioner's LP-PLA2 test. The Petitioner appealed

BCBSM's denial through the internal grievance process. After a managerial-level conference on January 23, 2008, BCBSM did not change its decision and issued a final adverse determination dated January 25, 2008.

# III ISSUE

Did BCBSM properly deny coverage for the Petitioner's LP-PLA2 lab test?

# IV ANALYSIS

## Petitioner's Argument

The Petitioner's doctor ordered the LP-PLA2 lab test because he believed that it was medically necessary for treatment of her high cholesterol and for management of her atherosclerosis. The Petitioner believes that this test is a covered benefit and BCBSM is required to pay for it.

## BCBSM's Argument

Under the provisions of the certificate, BCBSM does not pay for experimental treatment or services related to experimental treatment. BCBSM's medical director reviewed the documentation and concluded that the test for LP-PLA2 is considered safe but its effectiveness and usefulness in the clinical management of atherosclerosis has not been scientifically determined. Therefore, BCBSM says it meets the definition of experimental and is not covered.

#### Commissioner's Review

The Petitioner's certificate sets forth the benefits that are covered. In Section 6: General Conditions of Your Contract, it says (page 6.3):

We do not pay for experimental treatment (including experimental drugs or devices) or services related to experimental treatment, except 1 as explained under "Services That Are Payable" below.

Also, the certificate, in Section 7: The Language of Health Care on page 7.7, defines

<sup>&</sup>lt;sup>1</sup> The experimental treatment exceptions deal only with services in an approved oncology clinical. There is no indication that cancer is involved in this case and therefore the exceptions do not apply.

"experimental treatment" as:

Treatment that has not been scientifically proven to be as safe and effective for treatment of the patient's condition as conventional treatment.

The question of whether the Petitioner's LP-PLA2 test is considered experimental in nature was presented to an IRO for analysis as required by section 11(6) of PRIRA, MCL 550.1911(6). The IRO physician reviewer is board certified in internal medicine.

The IRO reviewer is knowledgeable and has reviewed the recent literature regarding the laboratory test in question and is familiar with the National Cholesterol Education Program (NCEP) guidelines for risk stratification for cardiovascular disease (CVD). The IRO reviewer indicated that the LP-PLA2 test is a measurement of an inflammatory marker that has been shown in case control studies to be positively associated with coronary event risk. Additionally, in a systematic review of the literature by Garza et al, Mayo Clinical Proceeding 2007, Feb: 82(2): 159-165, the LP-PLA2 level was shown to be "significantly associated with CVD." Although the LP-PLA2 level is potentially a predictor of CVD, there is no available pharmacologic intervention to lower this level, and it is not a therapeutic target for CVD risk reduction.

Given the explanation of "experimental treatment" in the Petitioner's certificate the IRO reviewer concluded that

this test is safe but investigational because there is inadequate medical literature or clinical experience to support its use in treating the [Petitioner's] condition. It is not clear that the results of this test have any benefit over and above tests that are ordered in usual standard of care. It is also not clear that the results would alter the [Petitioner's] current therapeutic plan.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, the IRO recommendation is afforded deference by the Commissioner; in a decision to uphold or reverse an adverse determination the Commissioner must cite "the principal reason or reasons why the commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16) (b). The IRO reviewer's analysis is based on extensive expertise and professional judgment and the Commissioner can discern no reason why the

recommendation should be rejected in the present case.

The Commissioner accepts the conclusion of the IRO and finds that the Petitioner's LP-PLA2 test is experimental for treatment of her condition and therefore is not a covered benefit under the certificate.

# V ORDER

Respondent BCBSM's January 25, 2008, final adverse determination is upheld. BCBSM is not required to cover the Petitioner's March 23, 2007, LP-PLA2 test.

Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than sixty days from the date of this Order in the circuit court for the county where the covered person resides or the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of the Office of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.